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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,936	09/22/2003	John Moberg	1001.1715101	1606

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EXAMINER	
LALLI, MELISSA LYNN	
ART UNIT	**PAPER NUMBER**
3728	

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07/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,936	MOBERG, JOHN	
	Examiner	Art Unit	
	MELISSA L. LALLI	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *5, 6, 14-18, 22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-13,19-21 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/03, 3/24/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment received on May 12, 2008 has been acknowledged. Species 1 including claims 1-4, 7-13, 19-21, and 24-26 is elected and claims 5, 6, 14-18, 22, and 23 are withdrawn. Therefore, claims 1-4, 7-13, 19-21, and 24-26 are pending.

Oath or Declaration

2. The Office is hereby *sua sponte* waiving the express language requirement or 37 CFR 1.63(b)(3), where the oath or declaration was filed prior to 01 June 2008. The express language of 37 CFR 1.63(b)(3) is waived only to the extent necessary such that an oath or declaration containing the "material to examination" or "in accordance with § 1.56(a)" language, or both, will be accepted as acknowledging the applicant's duty to disclose information "material to patentability" as defined in 37 CFR 1.56. Applicants are advised that, notwithstanding the preceding waiver, an applicant who has not disclosed information that is material to patentability as defined in 37 CFR 1.56, because it was believed that the information was not "material to the examination," should disclose such information in order to discharge the applicant's duty of disclosure as required by 37 CFR 1.56, and should file a supplemental oath or declaration acknowledging that duty of disclosure.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 7-13, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,419,764 to Roll.

Regarding claim 1, Roll discloses an elongate medical device (fig. 2) suitable for packaging in a tubular member (106) having a lumen defined by an inner surface, the elongate medical device comprising: an elongate shaft (113), a hub assembly (104) connected to the elongate shaft and including a portion manufactured from a first material; and an interference fit member (105) including a second material (abstract, line 19) and disposed about a portion of the hub assembly and configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the interference fit member (IFM) are disposed within the lumen of the tubular member (fig. 3).

Regarding claims 7-13, Roll discloses the second material (rubber) being more compressible than and readily deformable compared to the first material (fig. 2). Rubber is an elastomeric material and the IFM is disclosed as being an O-ring (col. 3, lines 6-10). Silicone is a form of rubber. The O-ring can be considered a bead adhered to the first material or an elongated elastomeric sleeve.

Regarding claim 26, Roll discloses an elongate medical device packaging assembly (fig. 2) comprising: a tubular member (106) having a lumen defined by an inner surface, an elongate shaft (113) with a proximal portion, a hub assembly (104) connected to the proximal portion of the elongate shaft and including a portion manufactured from a first material; and an IFM (105) including a second material (abstract, line 19) and disposed about a portion of the hub assembly and configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the IFM are disposed within the lumen of the tubular member (fig. 2).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-4, 7-11, 13, 19-21, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,214,220 to McGlinch et al. (McGlinch) in view of U.S. Patent No. 5,217,114 to Gadberry et al. (Gadberry).

Regarding claim 1, McGlinch discloses an elongate medical device (20) suitable for packaging in a tubular member (10) having a lumen (14) defined by an inner surface, the elongate medical device comprising: an elongate shaft (22), a hub assembly (30) connected to the elongate shaft and including a portion manufactured from a first material (col. 3, lines 13-18); and an IFM (40) disposed about a portion of the hub assembly and configured to form an interference fit with the inner surface of the tubular

member when the elongate shaft and the IFM are disposed within the lumen of the tubular member (fig. 1). McGlinch does not disclose the IFM including a second material; however, Gadberry discloses a similar elongate medical device (12) suitable for packaging in a tubular member (23) with an IFM (65) including a second material (figs. 3 and 6, the IFM is readily deformable compared to the tubular member). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the IFM (65) including a second material of Gadberry for the IFM (40) of McGlinch in order to create an air tight seal when enclosing the elongate medical device as taught by Gadberry (col. 5, lines 33-36).

Regarding claim 2, according to the modification of McGlinch by Gadberry as discussed in the rejection of claim 1 above, McGlinch discloses the hub assembly (30) having a distal portion including a segment with a generally circular cross section including a first material (fig. 1). Gadberry discloses the IFM (65) being disposed about a channel (64) extending circumferentially around the tubular member (23). It would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated the channel (64) of Gadberry on the circular segment of the distal portion of the hub assembly (30) of McGlinch in order to facilitate removal of the elongate medical device from the tubular member while creating the appropriate amount of friction to keep the seal air tight when the elongate medical device is enclosed as taught by Gadberry.

Regarding claim 19, McGlinch discloses an elongate medical device (20) suitable for packaging in a tubular member (10) having a lumen (14) defined by an inner surface,

the elongate medical device comprising: an elongate shaft (22) having a proximal portion, a hub assembly (30) connected to the proximal portion of the elongate shaft and including a portion manufactured from a first material (col. 3, lines 13-18); and a circumferential IFM (40) configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the IFM are disposed within the lumen of the tubular member (fig. 1). McGlinch does not disclose the hub assembly including a circumferential channel and the IFM being disposed about a portion of the circumferential channel and comprising an elastomeric material; however, Gadberry discloses a similar elongate medical device (12) suitable for packaging in a tubular member (23) with a circumferential IFM (65) disposed about a circumferential channel (64) and comprising an elastomeric material (figs. 3 and 6, the IFM is readily deformable compared to the tubular member). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the circumferential channel (64) and elastomeric IFM (65) arrangement of Gadberry for the IFM (40) on the hub assembly (30) of McGlinch in order to facilitate removal of the elongate medical device from the tubular member while creating the appropriate amount of friction to keep the seal air tight when the elongate medical device is enclosed as taught by Gadberry.

Regarding claims 3, 4, 20, and 21, according to the modification of McGlinch by Gadberry as discussed in the rejections of claims 1 and 19 above, McGlinch discloses the hub assembly (30) comprising a manifold (32) with a distal portion including the first material where the IFM is disposed about the distal portion of the manifold. A strain relief member (34) is integrally formed with the manifold (col. 3, lines 9-13).

Regarding claims 7-11, and 13, 24 and 25, according to the modification of McGlinch by Gadberry as discussed in the rejections of claims 1 and 19 above, Gadberry discloses the second material being more compressible than and readily deformable compared to the first material (figs. 3 and 6). The second material is considered elastomeric and the IFM is disclosed as an O-ring (col. 4, lines 25-27). The O-ring can be considered a bead adhered to the first material or an elongated elastomeric sleeve.

Regarding claim 26, McGlinch discloses an elongate medical device packaging assembly (fig. 1) comprising: a tubular member (10) having a lumen (14) defined by an inner surface; an elongate shaft (22) having a proximal portion, a hub assembly (30) connected to the proximal portion of the elongate shaft and including a portion manufactured from a first material (col. 3, lines 13-18); and an IFM (40) disposed about a portion of the hub assembly and configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the IFM are disposed within the lumen of the tubular member (fig. 1). McGlinch does not disclose the IFM including a second material; however, Gadberry discloses a similar elongate medical device packaging assembly (10) having a tubular member (23) with an IFM (65) including a second material (figs. 3 and 6, the IFM is readily deformable compared to the tubular member). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the IFM (65) including a second material of Gadberry for the IFM (40) of McGlinch in order to create an air tight seal when enclosing the elongate medical device as taught by Gadberry (col. 5, lines 33-36).

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGlinch and Gadberry in view of Roll.

Regarding claim 12, according to the modification of McGlinch by Gadberry as discussed in the rejection of claims 1 above, McGlinch and Gadberry do not disclose the O-ring (65) comprising silicone; however, Roll discloses a similar elongate medical device (fig. 2) suitable for packaging in a tubular member (106) with an O-ring (105) formed of rubber (abstract, line 19). Silicone is a form of rubber. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used silicone to form the O-ring used in the elongate medical device of McGlinch and Gadberry as it is well known in the art. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The U.S. Patent No.'s 5,941,849 and 6,042,577 have been included because they are relevant to the claimed subject matter.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA L. LALLI whose telephone number is (571)270-5056. The examiner can normally be reached on Monday-Friday 7:30 AM-5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa L Lalli/

Examiner, Art Unit 3728

/Bryon P. Gehman/
Primary Examiner, Art Unit 3728